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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/852,666	05/07/1997	KIRAN K. CHADA	UMD-1.0-037C	7255

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EXAMINER	
KAM, CHIH MIN	
ART UNIT	**PAPER NUMBER**
1653	46

DATE MAILED: 06/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/852,666	CHADA ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *55-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *55-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☒ Interview Summary (PTO-413) Paper No(s). *44* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of the Claims

1. Claims 55-62 are pending.

Applicants' amendments filed on April 8, 2003 (Paper No. 43) is acknowledged. Applicants' response has been fully considered. Claims 1-54 have been cancelled, and claims 55-60 have been amended. Therefore, claims 55-62 are examined.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

2. The previous rejection of claims 50, 53 and 54 under 35 U.S.C.112, first paragraph, is withdrawn in view of applicants' cancellation of the claim in Paper No. 43.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 55-62 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for screening candidate compounds capable of inhibiting HMGI biological activity, where the biological activity is to regulate the expression of a specified downstream target gene such as interferon-β gene, comprising (a) immobilizing an HMGI protein or a functional fragment on a solid surface, (b) incubating the HMGI protein or the functional fragment with a candidate compound, (c) identifying the compound which binds to the protein, (d) transfecting into a cell a DNA construct which contains a reporter gene under the

control of an HMGI protein-regulated promoter, (e) administering to the cell the candidate compound, (f) measuring the levels of reporter gene expression in the presence and absence of the compound, and (g) determining from the levels of reporter gene expression the compound which inhibits the HMGI biological activity, does not reasonably provide enablement for a method for screening candidate compounds capable of inhibiting HMGI biological activity where the biological activity of HMGI is to regulate the expression of a downstream target gene, but the target gene is not defined, comprising the steps of (a)-(c) and the step of determining whether the compound modulates HMGI biological activity from its ability to bind to the HMGI protein or the functional fragment, or, comprising the steps of (a)-(g). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claims 55-62 are directed to a method for screening candidate compounds capable of inhibiting HMGI biological activity by a binding assay comprising the steps of immobilizing an HMGI protein or a functional fragment on a solid surface and determining the compound modulating HMGI biological activity from its binding to HMGI or functional fragment (claims 55 and 56), or by a combination of the binding assay and a cell-based assay (claims 57-62). The specification, however, only discloses cursory conclusions without data supporting the findings, which states that a method for screening candidate compounds capable of inhibiting HMGI biological activity comprising the first step of immobilizing an HMGI protein or a fragment on a solid surface; or comprising the steps of transfecting into a cell a DNA construct and administering to the cell a candidate compound; or using a cell-based assay to isolating compounds which bind to HMGI proteins or their fragments (page 11, line 26-page 12, line 11;

page 54, paragraph 3). There are no indicia that the present application enables the full scope in view of a method for screening candidate compounds for inhibiting HMGI biological activity by either the binding assay or the combination of the binding assay and cell-based assay as discussed in the stated rejection. The present application provides no indicia and no teaching/guidance as to how the full scope of the claim is enabled. The factors considered in determining whether undue experimentation is required, are summarized in In re Wands (858 F2d at 731,737, 8 USPQ2d at 1400,1404 (Fed. Cir.1988)). The factors most relevant to this rejection are the breath of the claims, the absence of working examples, the state of the prior art and relative skill of those in the art, the unpredictability of the art, the nature of the art, the amount of direction or guidance presented, and the amount of experimentation necessary.

(1). The breath of the claims:

The breath of the claims is broad and encompasses unspecified variants regarding the biological activity of the HMGI protein, which is to regulate the expression of downstream target genes, but the target genes are not identified; and the compounds identified by the binding assay may or may not inhibit the biological activity of the HMGI protein, which are not adequately described or demonstrated in the specification.

(2). The absence of working examples:

There are no working examples indicating the claimed methods in association with the variants.

(3). The state of the prior art and relative skill of those in the art:

The prior art cited in the specification (page 54, lines 25-28) indicates the DNA binding domain of HMGI has a consensus sequence TPKRPRGRPKK, and the sequence of

PRGRPKGSKNK is implicated in protein-protein interactions involving HMGI proteins, a compound which binds to these areas may be identified by a binding assay, but the specification does not indicate the compound being tested in inhibiting the biological activity of HMGI. Moreover, the general knowledge and level of the skill in the art do not supplement the omitted description, the specification needs to provide specific guidance on how to monitor the biological activity of HMGI, e.g., identifying the downstream target genes, and the correlation between the binding of the identified compound to HMGI protein or its functional fragment and the inhibitory effect of the compound on the biological activity of HMGI protein, to be considered enabling for variants.

(4). Predictability or unpredictability of the art:

The claims encompass a method for screening candidate compounds capable of inhibiting HMGI biological activity by a binding assay, or a combination of the binding assay and cell-based assay. However, the specification does not describe how to monitor the biological activity of HMGI, nor demonstrates the compound identified by the binding assay or the combination assays inhibits the biological activity of HMGI, the invention is highly unpredictable regarding the outcome of the screening method.

(5). The amount of direction or guidance presented and the quantity of experimentation necessary:

The claims are directed to a method for screening candidate compounds capable of inhibiting HMGI biological activity by a binding assay, or a combination of the binding assay and cell-based assay. The specification indicates HMGI is the architectural component of the enhanceosome, and disruption of the enhancesome assembly by interfering either with protein-

DNA or protein-protein interactions of HMGI proteins results in loss of transcriptional regulation. Small molecules which have the same DNA-binding specificity as HMGI proteins such as netropsin, distamycin A and bisbenzimide can inhibit HMGI biological funtion (page 53, lines 20-36). However, the specification has not described the monitoring of the biological activity of HMGI except indicating in a cell-based assay, a DNA construct containing a reporter gene such as luciferase gene under control of a HMGI-regulated promoter such as human interferon-β promoter is transfected into a cell line which expresses proteins required for induction of human interferon-β gene such as NF-kb and HMGI genes (page 54, paragraph 3), nor has demonstrated any compound identified by the binding assay, or the combination of the two assays inhibits the biological acivity of HMGI. Furthermore, there is no working example demonstrating the claimed method. Since the specification fails to provide sufficient guidance on how to monitor the biological activity of HMGI, e.g., identification of the downstream target genes, and the inhibitory effects of the compounds identified by the claimed method, it is necessary to carry out further experimentation to identify the compounds by the claimed method and to assess their effects on the inhibition of the biological acivity of HMGI.

(6). Nature of the Invention

The scope of the claims encompass for screening candidate compounds capable of inhibiting HMGI biological activity by the binding assay, or the combination of the binding and cell-based assays, however, the specification has not demonstrated the compounds identified by the method inhibit the biological activity of HMGI. Thus, the disclosure is not enabling for the reasons discussed above.

In summary, the scope of the claim is broad, there is no working example demonstrating the claimed methods, the art is unpredictable regarding the outcome of the claimed methods, and the teaching are limited, therefore, it is necessary to have additional guidance to carry out further experimentation to assess the effect of the compound identified by the claimed method on inhibition of the biological activity of HMGI..

In response, applicants indicate the specification has described the biological activity of HMGI (page 3, lines 17-21; page 32, lines 4-9; page 53, lines 20-25), which is to form transcriptional regulatory complexes and to regulate transcription of downstream target genes, and the claims have been amended to include the explanation for the biological activity of HMGI (pages 5 and 6 of the response). Applicants' response has been fully considered, however, the argument is not found persuasive because the claim recites the biological activity of HMGI is to regulate expression of downstream target genes, however, the target genes are not specified. Furthermore, the specification does not describe the identities of these target genes and how to monitor the biological activity of HMGI as indicated in the section above.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 58 and 59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 58 and 59 are indefinite because the claim recites being dependent from itself.

Conclusion

5. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. CMK
Patent Examiner

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June 24, 2003

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